

CLAIMS

1-45. (Cancelled)

46. (Currently Amended) A liquid pharmaceutical composition, comprising:
a follicle stimulating hormone or a variant thereof,
m-cresol,
a diluent, and
~~at least one surfactant selected from the group consisting of poloxamer 188, poloxamer 217, poloxamer 237 and poloxamer 238,~~
the composition having a stability sufficient to avoid precipitation.

47. (Previously Presented) The composition according to Claim 46, wherein the follicle stimulating hormone is present in an amount of from 150 IU/ml to 1200 IU/ml.

48. (Previously Presented) The composition according to Claim 46, wherein the follicle stimulating hormone is present in an amount of from 300 IU/ml to 900 IU/ml.

49. (Previously Presented) The composition according to Claim 46, wherein the follicle stimulating hormone is present in an amount of about 600 IU/ml.

50. (Cancelled)

51. (Previously Presented) The composition according to Claim 46, wherein the follicle stimulating hormone is human follicle stimulating hormone.

52. (Previously Presented) The pharmaceutical composition according to Claim 46, wherein the follicle stimulating hormone is urinary human follicle stimulating hormone.

53. (Previously Presented) The composition according to Claim 46, wherein the follicle stimulating hormone is recombinant human follicle stimulating hormone.

54-55. (Cancelled)

56. (Previously Presented) The composition according to Claim 46, comprising m-cresol in an amount of about 0.3% by mass based on the mass of the diluent.

57. (Previously Presented) The composition according to Claim 46, further comprising sucrose.

58. (Previously Presented) The composition according to Claim 46, further comprising methionine.

59. (Previously Presented) The composition according to Claim 46, further comprising a phosphate buffer, wherein the pH of the composition is from 6.0 to 8.0.

60. (Previously Presented) The composition according to Claim 46, further comprising a phosphate buffer, wherein the pH of the composition is about 7.0.

61. (Previously Presented) The composition according to Claim 46, comprising the diluent, recombinant follicle stimulating hormone, poloxamer 188, sucrose, methionine, m-cresol, and an aqueous buffer, and wherein the pH of the composition is about 7.0.

62. (Previously Presented) The composition according to Claim 61, wherein the recombinant follicle stimulating hormone is present in an amount of about 600 IU/ml, the poloxamer 188 is present in an amount of about 0.1 mg/ml, the sucrose is present in an amount of about 60 mg/ml, the methionine is present in an amount of about 0.1 mg/ml, the m-cresol is present in an amount of about 3 mg/ml, and the phosphate buffer is present in an amount of about 10 mM in phosphate.

63 . (Previously Presented) The composition according to Claim 46, wherein the diluent is water for injection.

64 . (Previously Presented) The composition according to Claim 46, wherein the diluent is at least one of water and a mixture of water with a solvent miscible with water.

65.-71. (Cancelled)

72. (Currently Amended) A liquid pharmaceutical composition, comprising:

a follicle stimulating hormone or a variant thereof,
a luteinising hormone or a variant thereof,
a bacteriostatic agent selected from the group consisting of phenol and m-cresol,
~~at least one surfactant selected from the group consisting of poloxamer 188, poloxamer 217, poloxamer 237 and poloxamer 238, and~~
a diluent,
wherein the follicle stimulating hormone is human follicle stimulating hormone, the
luteinising hormone is human luteinising hormone, or the follicle stimulating hormone is human
follicle stimulating hormone and the luteinising hormone is human luteinising hormone,
the composition having a stability sufficient to avoid precipitation.

73. (Currently Amended) A liquid pharmaceutical composition, comprising:
a follicle stimulating hormone or a variant thereof,
a luteinising hormone or a variant thereof,
a bacteriostatic agent selected from the group consisting of phenol and m-cresol,
~~at least one surfactant selected from the group consisting of poloxamer 188, poloxamer 217, poloxamer 237 and poloxamer 238, and~~
a diluent,
wherein the follicle stimulating hormone is urinary human follicle stimulating hormone,
the luteinising hormone is urinary human luteinising hormone, or the follicle stimulating
hormone is urinary human follicle stimulating hormone and the luteinising hormone is urinary
human luteinising hormone,
the composition having a stability sufficient to avoid precipitation.

74. (Currently Amended) A liquid pharmaceutical composition, comprising:

a follicle stimulating hormone or a variant thereof,

a luteinising hormone or a variant thereof,

a bacteriostatic agent selected from the group consisting of phenol and m-cresol,

~~at least one surfactant selected from the group consisting of poloxamer 188, poloxamer~~

~~217, poloxamer 237 and poloxamer 238, and~~

a diluent,

wherein the follicle stimulating hormone is recombinant human follicle stimulating hormone, the luteinising hormone is recombinant human luteinising hormone, or the follicle stimulating hormone is recombinant human follicle stimulating hormone and the luteinising hormone is recombinant human luteinising hormone,

the composition having a stability sufficient to avoid precipitation.

75. (Previously Presented) The composition according to Claim 72, wherein the follicle stimulating hormone and the luteinising hormone are present in a ratio of from 6:1 to 1:6.

76. (Previously Presented) The composition according to Claim 72, wherein the follicle stimulating hormone and the luteinising hormone are present in a ratio of from 4:1 to 1:2.

77. (Previously Presented) The composition according to Claim 72, wherein the follicle stimulating hormone and the luteinising hormone are present in a ratio of from 3:1 to 1:1.

78. (Previously Presented) The composition according to Claim 72, wherein the follicle stimulating hormone and the luteinising hormone are present in a ratio of from 2:1 to 1:1.

79. (Currently Amended) The composition according to Claim 72, further comprising in which the bacteriostatic agent is phenol.

80. (Currently Amended) The composition according to Claim 72, further comprising in which the bacteriostatic agent is m-cresol.

81. (Cancelled)

82. (Previously Presented) The composition according to Claim 72, further comprising sucrose.

83. (Previously Presented) The composition according to Claim 72, further comprising methionine.

84. (Previously Presented) The composition according to Claim 72, further comprising a phosphate buffer, wherein the pH of the composition is from 6.0 to 8.0.

85. (Previously Presented) The composition according to Claim 72, further comprising a phosphate buffer, wherein the pH of the composition is about 7.0.

86. (Amended) The composition according to Claim 72, comprising the diluent, recombinant follicle stimulating hormone, luteinising hormone, poloxamer 188, sucrose, methionine, phenol, and an aqueous buffer, wherein the pH of the composition is about 7.0.

87. (Previously Presented) The composition according to Claim 86, wherein the recombinant follicle stimulating hormone is present in an amount of about 600 IU/ml, the poloxamer 188 is present in an amount of about 0.1 mg/ml, the sucrose is present in an amount of about 60 mg/ml, the methionine is present in an amount of about 0.1 mg/ml, the phenol is present in an amount of about 3 mg/ml, and the buffer is a phosphate buffer present in an amount of about 10 mM in phosphate.

88. (Previously Presented) The composition according to Claim 72, wherein the diluent is water for injection.

89. (Previously Presented) The composition according to Claim 72, wherein the diluent is at least one of water and a mixture of water and a solvent miscible with water.

90-188. (Cancelled)

189. (Previously Presented) The composition according to Claim 72, wherein the follicle stimulating hormone is present in an amount of from 150 IU/ml to 1200 IU/ml.

190. (Previously Presented) The composition according to Claim 72, wherein the follicle stimulating hormone is present in an amount of from 300 IU/ml to 900 IU/ml.

191. (Previously Presented) The composition according to Claim 72, wherein the follicle stimulating hormone is present in an amount of about 600 IU/ml.

192. (Previously Presented) The composition according to Claim 72, wherein the luteinising hormone is present in an amount of from 150 IU/ml to 1200 IU/ml.

193. (Previously Presented) The composition according to Claim 72, wherein the luteinising hormone is present in an amount of from 300 IU/ml to 750 IU/ml.

194. (Cancelled)

195. (Previously Presented) The composition according to Claim 86, wherein the luteinising hormone is recombinant luteinising hormone.

196. (Previously Presented) The composition according to Claim 195, wherein the follicle stimulating hormone and the luteinising hormone are present in a ratio of from 2:1.

197. (Previously Presented) The composition according to Claim 196, wherein the buffer is a phosphate buffer.

198. (Currently Amended) A liquid pharmaceutical composition, comprising:

a follicle stimulating hormone or a variant thereof,

phenol,

a diluent, and

~~at least one surfactant selected from the group consisting of poloxamer 188, poloxamer 217, poloxamer 237 and poloxamer 238,~~
the composition having a stability sufficient to avoid precipitation.

199. (Previously Presented) The composition according to Claim 198, wherein the follicle stimulating hormone is present in an amount of from 150 IU/ml to 1200 IU/ml.

200. (Previously Presented) The composition according to Claim 198, wherein the follicle stimulating hormone is present in an amount of from 300 IU/ml to 900 IU/ml.

201. (Previously Presented) The composition according to Claim 198, wherein the follicle stimulating hormone is present in an amount of about 600 IU/ml.

202. (Cancelled)

203. (Previously Presented) The composition according to Claim 198, wherein the follicle stimulating hormone is human follicle stimulating hormone.

204. (Previously Presented) The pharmaceutical composition according to Claim 198, wherein the follicle stimulating hormone is urinary human follicle stimulating hormone.

205. (Previously Presented) The composition according to Claim 198, wherein the follicle stimulating hormone is recombinant human follicle stimulating hormone.

206. (Previously Presented) The composition according to Claim 198, further comprising sucrose.

207. (Previously Presented) The composition according to Claim 198, further comprising methionine.

208. (Previously Presented) The composition according to Claim 198, further comprising a phosphate buffer, wherein the pH of the composition is from 6.0 to 8.0.

209. (Previously Presented) The composition according to Claim 198, further comprising a phosphate buffer, wherein the pH of the composition is about 7.0.

210. (Previously Presented) The composition according to Claim 198, wherein the diluent is water for injection.

211. (Previously Presented) The composition according to Claim 198, wherein the diluent is at least one of water and a mixture of water with a solvent miscible with water.

212. (New) The composition according to Claim 46 consisting essentially of recombinant follicle stimulating hormone, m-cresol, diluent, poloxamer 188, sucrose, methionine, and phosphate buffer.

213. (New) The composition according to Claim 212, wherein the recombinant follicle stimulating hormone is present in an amount of about 600 IU/ml, the m-cresol is present in an amount of about 3 mg/ml, the poloxamer 188 is present in an amount of about 0.1 mg/ml, the sucrose is present in an amount of about 60 mg/ml, the methionine is present in an amount of about 0.1 mg/ml, and the phosphate buffer is present in an amount of about 10 mM in phosphate.

214. (New) The composition according to Claim 72 consisting essentially of the diluent, recombinant follicle stimulating hormone, recombinant luteinising hormone, phenol, diluent, poloxamer 188, sucrose, methionine, and phosphate buffer.

215. (New) The composition according to Claim 214, wherein the recombinant follicle stimulating hormone is present in an amount of about 600 IU/ml, the recombinant luteinising hormone is present in an amount of about 300 IU/ml, the poloxamer 188 is present in an amount of about 0.25 mg/ml, the sucrose is present in an amount of about 77 mg/ml, and the methionine is present in an amount of about 0.15 mg/ml.